5. 510(k) Summary, XeraCem™

5.1. Submitter

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AUG 21 2008

Date Prepared: May 19, 2008

5.2. Device Name and Name/Address of Sponsor

XeraCem™
Doxa Dental AB
Axel Johanssons gata 4-6, SE 754 51
Uppsala, Sweden

Common or Usual Name

Dental Cement

Classification name

Dental cement other than zinc oxide-eugenol (21 CRF 872.3275)

Product Code

EMA

5.3. Predicate Devices

Trade name	510(k) holder	510(k) No.
Ketac™ Cem Maxicap™	ESPE GMBH	K897188
DoxaDent™	Doxa Certex AB	K011839

5.4. Intended Use/Indications for Use

XeraCem is a hybrid between glass ionomer cement and ceramic cement based on calcium aluminate. It combines the advantages of glass ionomer cements with those of calcium aluminum based cements. XeraCem is a hand mixed cement and consists of a powder (XeraCem powder) and a liquid (XeraCem liquid).

XeraCem is intended for the permanent cementation of

- Porcelain Fused to Metal Crowns and Bridges
- Metal (gold etc.) crowns and bridges
- Gold inlays and onlays
- Prefabricated metal and cast posts

- Prefabricated metal provisional crowns
- All-zirconia or all-alumina ceramic crowns and bridges

5.5. Technological characteristics

XeraCem is a hybrid glass ionomer-ceramic dental cement, reconstituted prior to use by hand mixing the XeraCem powder with the XeraCem liquid.

5.5. Performance Data

XeraCem is technologically identical to the previously cleared Ketac Cem Maxicap. Various physical and mechanical studies were conducted to compare XeraCem to the predicate devices. XeraCem has been evaluated and passed biocompatibility testing of cytotoxicity, genotoxicity, irritation, and sensitization. In all instances, XeraCem functioned as intended and the performance observed was as expected.

5.6. Substantial Equivalence

XeraCem is as safe and effective as the predicate devices. XeraCem has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Thus, XeraCem is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Doxa Dental AB
C/o Mr. Jonathan Kahan
Regulatory Counsel
Hogan & Hartson LLP
555 Thirteenth Street, NW
Columbia Square
Washington, DC 20004

AUG 21 2008

Re: K081405
Trade/Device Name: XeraCem™
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: August 18, 2008
Received: August 18, 2008

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use, XeraCem™

510(k) Number (if known): K081405

Device Name: XeraCem™

Indications for Use:

XeraCem is intended for the permanent cementation of

- Porcelain Fused to Metal Crowns and Bridges
- Metal (gold etc.) crowns and bridges
- Gold inlays and onlays
- Prefabricated metal and cast posts
- Prefabricated metal provisional crowns
- All-zirconia or all-alumina ceramic crowns and bridges

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081405